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Feng Xu

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27476

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NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

Claims 14-22 have been canceled. Claims 23-44 have been added. Claims 1-13 and 23-44 are pending and under consideration.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, 23-29, 34-40 drawn to a method for in vivo expression of an immunogen comprising administering a bacterial or mycobacterial cell comprising a polynucleotide encoding an immunogen to a mammal, wherein the bacteria is unable to use its own machinery to express the immunogen.

Group II, claim(s) 1-13, 23, 30, 31, 34, 41, 42 drawn to a method for in vivo expression of an immunogen comprising administering a yeast cell comprising a polynucleotide encoding an immunogen to a mammal, wherein the yeast is unable to use its own machinery to express the immunogen.

Group III, claim(s) 1-13, 23, 32, 33, 34, 43, 44 drawn to a method for in vivo expression of an immunogen comprising administering an insect cell comprising a polynucleotide encoding an immunogen to a mammal, wherein the insect cell is unable to use its own machinery to express the immunogen.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Li (J. Allergy Clin. Immunol. July 2003, Vol. 112, pg 159-167) taught the method of claims 1, 2, 5-9, 12, 13, 23, 24, 26, 34, 35, 36, 37 as supported by Burks

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(International archives of allergy and immunology, 1999, Vol. 118, pg 313-314),

Novagen pET system Manual, 2006 and US Patent 5,126,251.

Li administered inactivated heat killed E. coli comprising a plasmid encoding peanut antigen to mice (pg 160, col. 2, preparation of HKE-MP123), which generated an immune response against the antigen (pg 161, col. 2, "Results"). The E. coli inherently are "unable to use its own machinery to express the encoded immunogen" because it is heat killed. The polynucleotide encoding the peanut antigens inherently "comprises a promoter functional in eukaryotic cells" because it was made according to the method of Burks (pg 160, col. 2, "Preparation of HKE-MP123", citation 15). Burks taught the peanut antigens were inserted into pET24 plasmids (pg 313, col. 2, lines 8-12). The target genes in pET24 plasmids are under control of strong bacteriophage T7 (Novagen pET system Manual; pg 3, first full paragraph). US Patent 5,126,251 taught target genes under the control of T7 promoter expressed in mammalian cells. Therefore, the promoter of Li is "functional in eukaryotic cells."

Accordingly, the special technical feature: administering an inactivated non-mammalian cell to a mammal, wherein the non-mammalian cell comprises a nucleic acid sequence encoding an immunogen under the control of a promoter that functions in eukaryotic cells, is not a contribution over the prior art.

Furthermore, the structure and function of bacteria, yeast and insect cells are materially distinct and separate. In fact, each cell type is classified differently. The burden required to search all three cell types together would be undue.

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Currently, claims 1-13, 23 and 34 are generic to bacteria, mycobacteria, yeast and insect cells.

This application contains claims directed to more than one species of bacteria, yeast and insect cells. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The bacteria species are as follows: *E. coli*, *Shigella* spp, *Bordella* spp, *Salmonella* spp, *Bacillus* spp, *Streptococcus* spp, and *Mycobacteria* spp.

The yeast species are as follows: *Saccharomyces* spp and *Streptomyces* spp.

The insect cell species are as follows: *Aedes aegypti*, *Autographica California*, *Bombyx mori*, *Drosophila melanogaster*, *Spodoptera frugiperda*, and *Trichoplusia ni*.

If applicants elect Group I, applicants must elect a species of bacteria for examination.

If applicants elect Group II, applicants must elect a yeast species for examination.

If applicants elect Group III, applicants must elect species of insect cell for examination.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-13, 23-25, 34-36 are generic to bacteria. Claims 26 and 37 are specific to *E. coli*. Claims 27 and 38 are specific to *Shigella flexneri*. Claims 28 and 39 are specific to *Mycobacterium bovis*. Claims 29 and 40 are specific to *Salmonella typhi* TY21a.

Claims 1-13, 23, 30, 31, 34, 41, 42 are generic to yeast.

Claims 1-13, 23, 32, 33, 34, 43, 44 are generic to insect cells.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each type of bacteria has a different structure and different function in mammals. The bacteria are classified differently and the burden required to search them all together would be undue.

Likewise each yeast and insect cell listed has a different structure and different function

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in mammals. The species of yeasts and the species of insect cells are classified differently and the burden required to search them all together would be undue.

### ***Conclusion***

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/  
Patent Examiner